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L10: Entry 36 of 37

File: USPT

Aug 27, 2002

DOCUMENT-IDENTIFIER: US 6442432 B2

TITLE: Instrumentation and software for remote monitoring and programming of implantable medical devices (IMDs)

Brief Summary Text (2):

The present invention generally relates to implantable medical devices (IMDs). Specifically, the invention relates to a system providing real-time communication between the IMDs, medical instruments associated with or compatible with the IMDs, and a specialized remote expert data center, a central IMD support information network, or other remote collaborators. A display may be provided to allow users, particularly remote users, to track connection status and progress. More specifically, the invention relates to a central network to provide for a easily-accessed connection to the expert data center, central IMD information center, or other remote collaborators to promote reliable real-time connectivity between clinicians, IMDs and related medical devices as well as providing remote monitoring for proactive patient therapy and clinical care. The expert data center may be a web-enabled remote server which stores device registration and patient management data.

Brief Summary Text (10):

In addition to the patient concerns described above, the implantation and ongoing administration of a medical device must be carefully documented or recorded by various clinicians and commercial entities. For example, a clinician may wish to record information about the device such as its serial and model number in order to inform the patient of any firmware or software updates or upgrades involving the device, and to issue reminders to the patient regarding significant dates involving the IMD in order to generally aid in patient compliance. The IMD may also have a regular maintenance period suggested or prescribed, for example, for renewal of a power supply or refill of a reservoir containing a drug administered by the device. Similarly, the manufacturer and/or seller of the device will probably wish to record information about the device such as its serial and model number, manufacturing date, its batch or lot, the patient receiving the implant, the clinical entity administering the device, and the like, in order to ensure than any important information that may involve the device may be promptly provided to the patient either directly or indirectly. In addition, the manufacturer may be engaged in demographic or cohort clinical studies or data collection regarding etiological and device outcome scenarios across a population receiving a certain medical device or general category of medical device. Furthermore, the manufacture may wish to track demand of various product lines in order to determine which products or types of products are subject to greater demand, and accordingly should receive a greater investment of health care research and supply funds. In particular, the manufacturer will wish to maximize the likelihood that an implantable medical device will be available to a patient that needs one.

Brief Summary Text (11):

In general, then, the administration of an IMD may require ongoing involvement by various clinicians and medical personnel, the decisions and input of whom may materially affect the decisions that the other involved clinicians make on an ongoing basis. Accordingly, collaboration between these clinicians and coordination of their various treatment decisions and prescriptions is desirable. However, the

mobile nature of the modern medical professional's practice is well-known. A single physician, for example, may be affiliated with multiple different hospitals, offices, and other clinical settings, as well as with various corporate and professional entities. In addition, the typical clinician's busy schedule often makes it difficult if not impossible to predict where he or she may be reached at a particular time. The profession's relatively early deployment of pager technology is demonstrative of the highly mobile character of medical practice. Further complicating the ability of clinicians to communicate with each other is the fact that they are frequently involved in medical procedures where interruptions are, at best, inconvenient. In general, a medical professional may have multiple and unpredictable phone numbers leading to uncertainty as to where they can be reached, particularly with regard to wired telephone devices presently most suitable for reliable data transfer.

Brief Summary Text (16) :

Specifically, the communication scheme should be tailored to enable real-time communication between the remote data center, the programmer or an interface medical unit and the IMDs. The present invention provides a central network or "switchboard" to facilitate remote connectivity of programmers, IMDs and a preferably web-based expert data/management center to dispense real-time therapy and clinical care to patients worldwide.

Brief Summary Text (24) :

According to an embodiment of the present invention, medical instruments are further provided with a display that allows the user to observe that a connection to the electronic switchboard has been made, and to make a choice to either transfer data, wait for a collaboration partner to sign on, or choose a collaboration partner from those currently on-line. This display may, for example, be implemented as a local computer monitor connected to the medical device, or may be a hardware component of the medical device. A medical instrument configured to implement the present invention will have the ability to establish and maintain a connection, for example, via telephone line or data network to the central data network. In a preferred embodiment of the subject invention, the central data repository electronic switchboard maintains a connection with each logged-on instrument, and routes each instrument to either the network server for data transfer, or to another instrument that is on-line as chosen by the user. The central data repository network will preferably represent each on-line instrument to other instruments with a unique identifier. This may be, for example, a name, a device serial number, an avatar, i.e. a pictorial or other schematic representation of the device, or another suitable unique identifier. Users and operators of medical instruments and devices may select other medical devices connected to the network by means of this unique identifier. The network may provide various remote users and medical devices and/or their operators with a menu or list of all medical devices which may be accessed, according to their unique identification.

Brief Summary Text (26) :

In this way, the present invention provides a system for directing and facilitating central collaboration of IMDs implanted in patients, even when the patients are in a location remote from necessary equipment or the clinicians trained in operating the equipment. In one embodiment, the invention may be used to reduce or eliminate the need for a clinician or other person available to administer device administration. The invention may also create a means for gathering device data in advance of its actual review of a clinician. In this embodiment of the invention, a computer remote to the host patient may initiate and subsequently store the contents of IMD device memory uploaded and transmitted to the remote computer. This data would then be available for examination in the future. For example, a referring physician could use the ability to examine the patient remotely as a consultation system.

Brief Summary Text (27) :

In one embodiment of the present invention, a programmer unit or other interface medical unit that would connect to the centralized data network and repository may be provided. This central repository may be termed, for example, a remote data center. This remote data center will preferably provide access to an expert system allowing for downloading of upgrade data or other expert medical or device information to a local, i.e., IMD or communications device environment. Further, the invention may be implemented, for example, as an integrated software system for efficient voice and data communications to transfer information between the IMDs and a remote expert data center for dispensation of therapy and clinical care on a real-time basis.

Brief Summary Text (28):

Further, in one embodiment of the present invention, it is possible to enable the gathering of high resolution diagnostic/physiologic data, and to transfer information between the IMDs and a remote data center to dispense therapy and clinical care on a real-time basis. Further, the data system contemplated by the present invention enables an efficient system for data storage, collection and processing to effect changes in control algorithms of the IMDs and associated medical units to promote real-time therapy and clinical care.

Brief Summary Text (29):

The proliferation of patients with multi-implant medical devices worldwide has made it imperative to provide remote services to the IMDs and timely clinical care to the patient. The use of programmers and related interface devices to communicate with the IMDs and provide various remote services has become an important aspect of patient care. In addition to the instant invention, the use of programmers may be implemented in a manner consistent with the co-pending applications detailed in the foregoing Cross Reference to Related Applications, and assigned to the assignee of the instant invention. In light of the disclosures of these incorporated references, the present invention provides a vital system and method of delivering efficient therapy and clinical care to the patient.

Brief Summary Text (30):

In a representative embodiment of the instant invention, one or more IMDs, such as a pacemaker, defibrillator, drug pump, neurological stimulator, physiological signal recorder may be deployed in a patient. This IMD may be equipped with a radio frequency transmitter or receiver, or an alternate wireless communication telemetry technique or media which may travel through human tissue. For example, the IMD may contain a transmission device capable of transmitting through human tissue such as radio frequency telemetry, acoustic telemetry, or a transmission technique that uses patient tissue as a transmission medium. Alternately, an IMD may be deployed in a fashion by which a transmission or receiving device is visible externally to the patient but is connected directly or via wires to the IMD. An external device, which may generally be termed an interface medical device or interface medical unit, may be positioned outside the patient, the interface medical device being equipped with a radio frequency or other communication means compatible with the communication media of the IMD or the IMD transmitter/receiver, which may be external to the IMD and may further be external to the patient. Communication may be effected between the IMD transmitter/receiver and the external interface medical device, e.g. via radio frequency. The interface medical device may be connected via a wireless or physical communication media, e.g. via modem and direct dial connection, with the central expert computer or network. In an alternate embodiment of the subject invention, the interface medical device may have a direct connection or tunneled connection directly to the central network. In yet another alternate embodiment of the subject invention, the system may be implemented as a data network that allows the interface medical device access to the central expert network and various distributed devices from many locations, for example providing for an interface medical device that is portable.

Brief Summary Text (36):

In a preferred embodiment, the central collaboration network of the present invention is implemented as a software application which may be run on a server or central computer accessible via a network or direct connection by the interface medical device. In an alternate embodiment, the interface medical device may be implemented as a software client which may run on a computer remotely from the collaboration server. Preferably, the central collaboration computer, program or device is capable of autonomously and dynamically determining the model of an IMD, for example, according to manufacturer, type, and model number, as well as the specific serial number of a particular device. When an IMD is within communication range of an interface medical device, the central collaboration computer of the present invention is also preferably capable of configuring a deployed IMD, or commanding the interface medical device to retrieve data from the IMD.

Brief Summary Text (38) :

In a preferred embodiment, the central collaboration network and expert system of the present invention is implemented as a software application which may be run on a server or central computer accessible via a network or direct connection by the interface device. In an alternate embodiment, the programmer may be implemented in part as a software client which may run on a computer remotely from the server. Preferably, either the interface medical unit or the central expert center is capable of autonomously and dynamically determining the model of an IMD, for example, according to manufacturer, type, and model number, as well as the specific serial number of a particular device. When an IMD is within communication range of an interface medical device, it is also preferably capable of configuring the deployed IMD, or commanding the interface medical unit to retrieve data from the IMD.

Detailed Description Text (3) :

Returning to the single IMD embodiment depicted in FIG. 1, IMD 112 is equipped with or linked to a transmission and receiving device such as a radio frequency telemetry device, also preferably implanted in a patient. The central collaborative network 114 computing center or central computer 120 preferably has sufficient computing power and storage capability to collect and process large amounts of data with regard to user, device and clinician location and scheduling. The patient is placed or places himself or herself in proximity to interface medical device 116. For example, interface medical device 116 may be placed in a patient's home, at their bedside perhaps, or may be placed in a community center, clinical office setting, nursing home, or other care facility. Interface medical device 116 may also be embodied in a portable device that may be carried by the patient, or by a clinician. Interface medical device 116, like IMD 112, contains or is linked to a communications media transmitter/receiver compatible with the type incorporated into or linked to IMD 112. In an illustrative embodiment of the subject invention, interface medical device 116 contains a radio frequency transmitter/receiver or similar radio frequency telemetry device establishing radio frequency link 122.

Detailed Description Text (5) :

In a preferred embodiment of the subject invention, rather than hard-coding a static address or phone number for remote medical device 124 into interface medical unit 116, a static identifier for one or more remote medical devices may be coded or programmed into interface unit 116. This identifier is preferably unique within collaborative network 114, but need not be unique among the entire world or among devices with access to a public network 114. For example, if central collaboration network 114 is implemented using the Internet, it is preferably not necessary to have each remote medical device 124 have a separate unique IP address coded into interface unit 116. Instead, the interface unit 116 identifies a target remote medical device 124 using an identifier that is unique within the system of the present invention. For example, the remote medical device 124 may be identified by a serial number, unique key name, or avatar visible on interface unit screen 116. Upon transmission of the unique identifier of the target remote medical device 116, the target device transmission information is preferably forwarded over central

collaboration network 114 to central computer 120. This central collaboration computer 120 will preferably be possessed of appreciably more computing power than possible with an IMD 112, in terms of processor speed, RAM available, and other data storage. Central collaboration computer 120 is large scale in comparison to such processors that are available for incorporation into an IMD 112. For example, some commercially-available personal computers may contain sufficient computing power to operate as a server capable of carrying out some collaboration tasks of the present invention. In a preferred embodiment of the subject invention, however, central collaboration computer 120 will be a mainframe, multi-processor supercomputer, or a multi-processor workstation, such as a type available from Silicon Graphics, Inc./SGI of Mountain View, Calif. Such relatively high-powered computing devices may be better suited to efficient routing and posting of collaborative communications.

Detailed Description Text (6):

Regardless of which computing device is used, in accordance with the present invention, the computing device will be configured as a server capable of communicating directly or indirectly with interface medical device 116. The central collaboration computer 120 will preferably have sufficient storage, either internal to the computer or linked to the computer as depicted in storage device 134 for the storage of massive amounts of clinician and device contact information, and of historical patient data from, for example, a particular patient having an IMD 112 in communication with central collaboration computer 120. Data storage element 134 may contain any suitable means of data storage, including but not limited to hard drive, or another readable/writable magnetic or optical storage. In a preferred embodiment of the subject invention, data storage element 134 has a redundant array of disks such as a redundant array of inexpensive disks (RAID) system. Preferably, central computer 120 has relatively direct access to data storage facility 134. On data storage facility 134, the various "real-world" locations, node points, network addresses, phone numbers, or other unique network and/or telecommunications nodes, addresses, locations, or phone numbers are stored for access by central computer 120. The stored telecommunications network location information may be stored according to any suitable data storage or database scheme to facilitate low-overhead and prompt selection of the real-world network node. For example, the unique system identifier attributed to a particular medical device 124 and corresponding network or telecommunications address, node or number may be stored in a linked list, tree, hash table, dual linked list, or other lookup table or suitable data structure or database scheme. The network location of remote medical device 124 may also be stored on expert/data server 136 in addition to or instead of data storage facility 134.

Detailed Description Text (7):

In addition to remote medical devices 124, interface medical unit 116 may also effect interfacing or collaborative communications sessions with telecommunications or data communications devices 126. These may include, without limitation, personal digital assistant (PDA) 138, cellular or wired telephone 140, pager 142, or remote clinician computer 144. Like remote medical devices 124, the network location, network address, dial-up phone number, or other nodal or location information of communications devices 126, are preferably stored in data storage media 134 in order to be accessed by central collaboration computer 120. Because some collaboration that users wish to effect over collaboration network 114 may be voice communication, collaboration network 114 and central collaboration computer 120 are capable of transmitting and routing voice communications, e.g., voice communication data packetized and transmitted using the TCP/IP protocol (voice over IP). In some cases, direct dial-up voice communication over Plain Old Telephone Service may be effected or facilitated using the central location and availability logging of central collaboration computer 120 together with automated dialing by central collaboration computer 120.

Detailed Description Text (8):

A third type of remote unit that may be accessed via central collaborative network 114 is remote computer 146. This remote computer 146 may implement the functions of a medical device, such as remote medical devices 124. Alternatively, remote computer 146 may be used by a human clinician to instruct or interact with interface unit 116, for example, instructing interface unit 116 to send instructions downloaded from remote expert server 136 to remote IMD 112. Remote computer 146 may display information not only from central collaboration computer 120, but also from remote medical devices 124. A clinician using remote computer 146 may also carry out interactive collaboration or "chat" sessions with other clinicians in order to discuss one or more possible clinical procedures or IMD programming strategies being considered, for example. These collaborative sessions may be carried out between a clinician on remote computer 146 and other clinicians using other remote computers 144 or 146 that may communicate with other remote computers 146 over collaborative network 114. Individual clinicians may log-in or register with central collaboration computer 120 in order to indicate their accessibility through the network at a certain place which may be monitored or logged by central collaboration computer 120. The clinician may be identified on the network by a unique identifier such as a user name. As an alternative to client interactions, and for scenarios in which not all interested participants may be on-line or otherwise available at one time, central collaboration computer 120 also preferably supports a "bulletin board" USENET groups, or newsgroups service, e.g., using NNTP.

Detailed Description Text (13) :

While interface medical unit 116 is portrayed primarily as a self-contained or stand-alone unit, it will be appreciated that interface medical unit 116 may also be implemented as a peripheral transmitter/receiver capable of wireless communication with IMD 112, and also in communication with a computer such as a personal computer such as a laptop or portable computer. Implemented on a computer, interface medical unit 116 may also be a terminal or client of a remote computer, including of central collaboration computer 120. It will be appreciated that in the event that interface medical unit 116 is implemented as a peripheral and terminal, some of the components of interface medical unit 116, e.g., storage component 224, may be implemented on central collaboration computer 120 or a storage device 134 accessible to central collaboration computer 120 rather than in the terminal implementing interface medical unit 116.

Detailed Description Text (15) :

Security and integrity of the patient information stored on the collaborative computer 120 or storage device 134 and IMD interface operation will preferably be closely guarded for at least the following reasons: First, patient physiologic data detected by a deployed IMD 112 will be transmitted via interface medical unit 116 to central collaboration computer 120 for purposes of analysis of this data, and treatment regimens and/or IMD 112 instructions, firmware, or software may be changed on the basis of this information and collaboration over network 114 as described above. Accordingly, integrity of transmitted data and instructions will preferably be maintained so as to avoid adverse patient outcomes or patient outcomes that do not take full advantage of the subject invention. In addition, patient information that may be linked to an identifiable individual is typically regarded as confidential. Accordingly, encryption or tunneling will preferably be provided to ensure patient confidentiality, particularly when transmissions between interface medical device 116 and central collaboration computer 120, or between central computer 120 and remote devices 124 or 126 takes place though media other than a dedicated line/direct dial-up connection, such as connection 230 in FIG. 2. For example, transmissions may be effected over a packet-based network technology over a public network or internetwork 114. For example, if the transmissions are routed over the Internet using TCP/IP, encryption will preferably be used. As an alternative to encryption, a proprietary data exchange format/interface or scripting language that is kept secret may be used in communications between IMD 112 and central collaboration computer 120. However, even with secure dedicated

lines 230 or a secret data format, digital signatures will preferably be used to detect corruption of data. Additional implementations of security systems may also be utilized in accordance with the subject invention, including biometric security apparatus and methods to detect inalterable physical characteristics of persons attempting to access the patient data via remote computer 146 in order to authenticate the would-be user of the system.

Detailed Description Text (16):

Security measures such as the foregoing will preferably be used to authenticate the interface medical device 116 and IMD 112, as well as persons attempting to access patient information, particularly individually identifiable patient information. Accordingly, a preferred embodiment of the subject invention utilizes digital signatures and encryption of the patient information and IMD 112 instructions being transmitted according to the present invention. Encryption of patient information will serve to protect patient confidentiality. Each transmission of patient data will preferably have a digital signature that can be checked against the transmission payload to ensure that patient data and IMD 112 instructions were not corrupted during transmission. Examples of encryption/digital signature schemes that should prove sufficient for suitable encryption of patient information and digital signatures include PGP, the RSA public key infrastructure scheme, or other consumer-level or higher, prime number based encryption signature scheme. Biometric data used to authenticate and verify accessors of the data may include retina scans, iris scans, fingerprint scans, veinprint scans, voiceprints, facial geometry/facial recognition according to facial nodal points, or hand geometry scans.

Detailed Description Text (18):

Transmissions between an IMD 112 and interface medical device 116 or between peripheral physiological data gatherer 232, or other peripheral devices will also preferably be protected from transmission errors using similar encryption, authentication, and verification techniques to those discussed above, and/or wireless communication enhancement techniques such as wireless modulation or another suitable wide-frequency spectra technique. Preferably, encryption and/or authentication will be effected end-to-end, i.e., covering the entire transmission from IMD 112 to central computer 120 or from computer 120 to IMD 112 or remote devices 124 or 126, rather than effecting one encryption/verification scheme between IMD 112 and interface medical device 116, and a different scheme between interface medical device 116 and central computer 120. As an alternative to, or in addition to the above authentication scheme, radio frequency pulse coding, spread spectrum, direct sequence, time-hopping, frequency hopping, a hybrid spread spectrum technique, or other wireless modulation techniques may be employed in order to reduce interference between IMD 112 and other IMD or other wireless devices, and to generally offer improved accuracy, reliability, and security to transmissions between IMD 112 and interface medical device 116, may be used to avoid cross-talk or confusion among IMDs and/or interface medical devices in proximity to each other. For example, radio coding may be implemented to avoid transmission errors or device confusion between neighboring IMD 112 patients utilizing a device implementing aspects of the present invention in a managed-care setting.

Detailed Description Text (19):

Upon establishment of a network connection, or direct dial-up connection, a communications link is established over which the interface medical device 116 may establish a connection with the central collaboration computer 120. Communication over collaboration network 114 may be effected by way of a TCP/IP connection, particularly one using the Internet, as well as a PSTN, DSL, ISDN, Cable Modem, LAN, WAN, MAN, direct dial-up connection, a dedicated line, or a dedicated terminal connection to a mainframe. The initial communication may focus on authentication of the interface medical device 116. This will preferably include verification that the interface medical device 116 is certified for interrogating IMDs, i.e., a

verification process has established that the software and hardware revisions are current, and that the authentication information uniquely identifies a specific known interface medical device 116.

Detailed Description Text (21):

In a representative embodiment of the invention, a device agent software module may be selected from remote expert server 136 to interface with a particular type or model of IMD 112. In an embodiment of the subject invention in which the interface medical unit 116 is configured to dynamically identify an IMD 112 presented to it for establishment of central collaboration, preferably an initial IMD 112 identification stage precedes the selection of device agent module. In an embodiment of the present invention configured or adapted for use with an in-home monitor device, preferably the interface medical device is pre-configured to work only with the specific device(s) implanted in an individual host patient of the residence.

CLAIMS:

4. The computerized method of claim 3, wherein the device information comprises at least one of device model number, serial number, hardware, firmware, or software identification patient name, patient contact information, clinician name, and clinician entity.
35. A computerized method of providing a communication link between an IMD and a remote medical resource, comprising the steps of: establishing a first communication path between the IMD and a central repository of medical device contact information; selecting a remote medical resource using resource-identifying access data; establishing a second communication path to the remote medical resource using the resource access data provided by the central repository.
42. The method of claim 38, wherein the remote device identifier comprises a unique patient identifier.
43. The method of claim 35 wherein the resource-identifying access data is data identifying the IMD.
45. The method of claim 43 wherein the data regarding the IMD is a unique IMD identifier.

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